REMARKS

The present amendment amends claims 1, 2, 3 and 6, without prejudice, and are intended to expedite prosecution on the merits. No new matter is introduced into the application by these amendments.

Reconsideration of this application, as amended, is respectfully requested.

Claims 1-22 are pending in the subject application,
- claims 11-18 have been withdrawn from consideration based on the prior restriction requirement being made final in the current Office Action, and, accordingly,
- claims 1-10 and 19-22 are currently under examination.

Objection

Claims 1-10 and 19-21 have been objected because of informalities in their use of abbreviations. The Examiner helpfully suggests that appropriate correction would involve spelling out the word or phrase being abbreviated in the first instance of use in the claims. Applicant has accordingly amended claims 1-3 and 6 as to spelling out the phrase or word(s) associated with the abbreviations: mAb, FIV, FIV-Shiz, gp and ATCC. It is believed that there are no other such unaccounted for abbreviations in the claims; and the objection is accordingly traversed.

§ 102 Rejection

Claims 1-8, 10 and 19-21 stand rejected as anticipated by Yamamoto (USP 5,275,813) under 35 U.S.C. 102(b). More specifically, the rejection cites Yamamoto as teaching a monoclonal antibody that binds to an inactivated FIV-encoded glycoprotein referring for support to col. 3, line 58, through col. 4, lines 63. The rejection continues that Yamamoto also teaches FIV isolates including FIV-Petaluma, as well as viral isolates inactivated by formalin; thus concludes the Examiner Yamamoto anticipates the limitations of claims 1-2, 4-6 and 10.

Applicant respectfully disagrees.

The column 3-4 reference made by the rejection is part of the Yamamoto specification described under "BRIEF DESCRIPTION OF THE DRAWINGS," and describes Figures 5A, 5B, 6A and 6B. That section relates that the immunogenicity of FIV produced from the disclosed FIV-infected cell lines was evaluated in cats, and the reactivities of the antibodies produced in cats immunized with either inactivated FIV-infected cell lines or with inactivated FIV produced from one of those cell lines were determined by immunoblot analysis. That section quoted also relates, inter alia, that cats were also immunized several (6) times with inactivated FIV-infected cells and uninfected cells and their serum immunoblot profiles were compared to those of serum from cats naturally infected or experimentally infected with FIV.

The inventors concluded/reported, beginning col. 4, line 41,

> "Our immunoblot analysis of the sera from immunized cats closely resembled the immunoblot profiles of FIV-infected cats previously published in our laboratories and others."

What Yamamoto told those skilled in the art is that whatever antibodies they used for testing, whether polyclonal, monoclonal, or some other multiclonal variation, (and it is pretty

apparent that the only reference is to polyclonal antibodies) those antibodies did not differentiate between the antibodies found in (live)- FIV-infected cats and inactivated FIV-infected cats. Thus Yamamoto discloses that the antibodies prepared and employed were not "specific for an epitope unique to an inactivated FIV-encoded glycoprotein."

Moreover, Yamamoto does not teach the preparation of any specific monoclonal antibody used in the testing/evaluation of the materials the results of which are reported in Figures 5A, 5B, 6A and 6B.

Accordingly, Yamamoto cannot possibly anticipate any of the claims and the rejection of claims 1-2, 4-6 and 10 under § 102 as anticipated based on Yamamoto has been traversed.

In respect of claims 3 and 8, the Examiner argues that these "claims limit the inactivated FIV-encoded glycoprotein to gp95." The Examiner, in the very next paragraph adds "even though Yamamoto does not literally teach a monoclonal antibody ..."

Applicant agrees that Yamamoto does not teach a monoclonal antibody. Therefore claims 3 and 8 are not anticipated.

In respect of claim 7, the rejection again argues that the antibody that Yamamoto teaches an antibody that binds to an FIV-encoded glycoprotein. Again, however, Yamamoto does not disclose a monoclonal antibody that binds uniquely to an inactivated FIV-encoded glycoprotein. It must be borne in mind that Yamamoto in reporting on the immunogenicity testing related in Figure 5 and 6 is reporting the results of immunizing animals with inactivated FIV, in one of two forms, and the immune response generated in the cats. The report discloses the test of the sera of those cats and relates that the immune response closely resembles that of naturally and/or experimentally FIV infected cats. No monoclonal has been prepared, and therefore Yamamoto cannot anticipate.

In further respect to claims 19-21, the Examiner asserts that Yamamoto teach a hybridoma cell line, and the use of a hybridoma cell line to obtain antibody – referring to col. 9, line 62 through line 40 of col. 10. Again, the rejection, in respect of claim 19, notes:
- that said claim is directed to a hybridoma cell line suitable for obtaining a particular antibody that binds to an inactivated FIV-encoded glycoprotein;
- that claim 20 requires that the cell line which is suitable for obtaining the monoclonal antibody specific for an epitope unique to an inactivated FIV-encoded glycoprotein selected from gp 95 and gp 130; and
- that claim 21, adds that said cell line is useful for obtaining mAb 1D9.

In these respects, the rejection again asserts that Yamamoto teaches a hybridoma cell line to obtain antibody and again admits that "... Yamamoto does not specifically teach the use of the hybridoma cell line to produce mAb 1D9 and antibody that binds to an inactivated FIV-encoded glycoprotein ..." Applicant again agrees, and that is why Yamamoto does not and cannot anticipate. Nevertheless, the rejection further argues that despite that admission, applicant has not disclosed sufficient particulars, and therefore Yamamoto anticipates. This rejection is not properly based as a § 102, and respectfully should be withdrawn.

Nevertheless, in a good faith effort to expedite prosecution, and without prejudice, claims 1 and 19, have been amended to note that the monoclonal antibody has the profile shown in Figure 1, basis for which is found, for example, on page 4 of the specification, line 20-22.

§ 103 Rejection

Claim 9 has also been rejected under 35 U.S.C. 103(a) as obvious over Yamamoto in view of Kakinuma. In this rejection, Yamamoto is cited as described, which applicant understands to mean that Yamamoto teaches antibodies and how to make, but does not teach an antibody that binds to an inactivated FIV-Shiz glycoprotein. However, argues the rejection, it would be obvious to make such an antibody since Yamamoto suggests that other isolates could be used with the teaching provided, and Kakinuma teaches that a certain degree of homology exists in the protein structure of various FIV isolates

Applicant strongly disagrees. As noted, Yamamoto does not teach what the Examiner suggests. What Yamamoto teaches is the use of inactivated FIV and inactivated FIV infected cells as an immunogen for treating FIV. Yamamoto also provides a general teaching on how to make monoclonal antibodies. Neither of these teachings provides any motivation to make the monoclonal antibody described in claim9, and Yamamoto has made no antibodies, even polyclonal, that was specific to detecting inactivated FIV as opposed to live FIV. For these reasons the combination of Yamamoto would not make obvious to one skilled in the art the monoclonal antibody of claim 9 at the time of the invention or provide a motivation or expectation of success.

§ 112 Rejections

Under Second Paragraph

Claims 1-10 and 19-21 stand rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as indefinite. The rejection asserts that the claims are directed to an antibody having a specific binding characteristic, but "it is unclear as to the epitope in which the antibody is required to bind." Similarly, the rejection notes the claim recitation "an epitope unique to an inactivated FIV-encoded glycoprotein" and inquires what is encompassed by "unique epitope" in which the claimed antibody binds, and further asserts that no additional insight is "rendered by the disclosure.

Applicant disagrees.

The question is whether the claims in question are clear to those skilled in the art. In this respect the claims relate that the monoclonal antibody of claims 1-10, and the hybridoma cell line suitable for obtaining such antibodies of claims 19-21, recite that the mAb is specific for an epitope unique to an inactivated FIV-encoded glycoprotein. Thus it is not specific for an epitope unique to a live FIV-encoded glycoprotein. This is a teaching of the invention, and this feature is evident in the claims and the specification, and the examples in the specification, which show a profile of the mAb in Figure 1, and demonstrates its specificity in Example 4. Thus the claims are not indefinite as suggested.

Reconsideration and withdrawal of the rejection under the first paragraph of 35 USC 112 is accordingly solicited. To expedite prosecution, kindly note that Claims 1 and 19 have in any event been amended without prejudice to recite that the mAb has the profile shown in Figure 1, reference to which is found in the specification, for example, on page 2, lines 20-22.

Under First Paragraph

Claims 6-7 and 22 have also been rejected under the first paragraph of 35 U.S.C. 112 as failing to comply with the enablement requirement. More specifically, the rejection notes that

the invention appears to relate to novel biological materials, and, as such, such material must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The rejection then argues that the specification does not disclose a repeatable process, and it is not apparent whether the biological material are otherwise available to the public.

Applicant respectfully traverses the rejection.

The preparation of the novel biological material is generally described in the specification and more specifically in the examples of the specification. A description of its preparation may be found, for example, beginning on page 4, line 5 of the specification. More specifics to the preparation are found beginning with Example 1, on page 5, including reference to the availability of various starting materials. Identification and features of the claimed mAb are also described in the specification, for example, on page 2, the section relating to a description off the drawing through the first 2 lines on page 3; on page 3, lines 19-25, disclosing with what the mAb does and does not react; on page 4, lines 24-28; and Example 4 which provides further features based on the evaluation of its specificity.

These teachings how to make and how to distinguish the monoclonal antibody of claims 6-7 and the cell line of claim 22 fully enable the skilled man in the art to repeatably prepare the biological materials claimed. Accordingly the rejection under the first paragraph of 35 USC 112 has respectfully been traversed.

The same rejection under the first paragraph of 35 U.S.C. 112 notes, in short, that the deposit information of the mAb referred to claims 6 and 22, does not provide all the information in the specification in proper form, and helpfully provides the new address of the ATCC.

The present amendment, to page 4 of the specification, evidencing the proper deposit of the organism having ATCC Accession No. PTA-4837 pursuant to the Budapest Treaty is addressed to this issue. Without comment as to the merits of the rejection, the amendment adds the complete name and full street address of the American Type Culture Collection depository to the specification. (It is noted to the Examiner that the Accession No. and the identity of the depository was already recited in the specification.)

Additionally, it is averred that the monoclonal antibody isolate designated mAb 1D9, having ATCC Accession No. PTA-4837, has been deposited and accepted in the American Type Culture Collection under the provisions of the Budapest Treaty. It is also averred that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of the patent on this application. A copy of the deposit receipt from the ATCC is enclosed for the convenience of the Examiner. It is noted that the deposit was first submitted October 9, 2002, and resubmitted on December 2, 2002, after the original deposit was deemed non-viable.

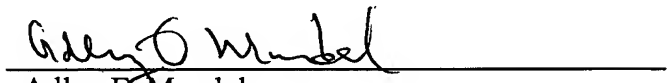
The present amendment does not present any new issues requiring further consideration or search and requires only a cursory review by the Examiner. The amendment introduces no new matter into the application.

Currently, Claims 11-18, which are drawn to the nonelected method claims, are being amended to include the same limitation as the examined claims, *i.e.*, the feature that the mAB "having the Western immunoblot analysis shown in Figure 1." If the Examiner finds that the pending claims are allowable, it is believed the withdrawn method Claims 11-18 are in condition to be rejoined and allowed together with the other claims.

Based on the foregoing, it is respectfully submitted that the invention defined herein is in condition for further prosecution and allowance. A timely notice of allowance is respectfully requested.

Please contact the undersigned if any matters may be resolved by a telephone conference.

Respectfully submitted,



Adley F. Mandel
Attorney for Applicants
Reg. No. 26,942

Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940
Tel. No. (973) 660-7659